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10/802,314	03/17/2004	Van Le Huynh	ECV-5539CON	3894
7590 EDWARDS LIFESCIENCES LLC One Edwards Way Irvine, CA 92614			EXAMINER PELLEGRINO, BRIAN E	
			ART UNIT 3738	PAPER NUMBER
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**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.



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**BEFORE THE BOARD OF PATENT APPEALS  
AND INTERFERENCES**

Application Number: 10/802,314  
Filing Date: March 17, 2004  
Appellant(s): HUYNH ET AL.

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Guy Cumberbatch  
For Appellant

**EXAMINER'S ANSWER**

This is in response to the supplemental reply filed 2/22/10 for the appeal brief submitted 9/22/08 appealing from the Office action mailed 3/20/08.

**(1) Real Party in Interest**

The examiner has no comment on the statement, or lack of statement, identifying by name the real party in interest in the brief.

**(2) Related Appeals and Interferences**

The examiner is not aware of any related appeals, interferences, or judicial proceedings which will directly affect or be directly affected by or have a bearing on the Board's decision in the pending appeal.

**(3) Status of Claims**

The following is a list of claims that are rejected and pending in the application:

Claims 1-21 are pending and rejected.

**(4) Status of Amendments After Final**

The examiner has no comment on the appellant's statement of the status of amendments after final rejection contained in the brief.

**(5) Summary of Claimed Subject Matter**

The examiner has no comment on the summary of claimed subject matter contained in the brief.

**(6) Grounds of Rejection to be Reviewed on Appeal**

The examiner has no comment on the appellant's statement of the grounds of rejection to be reviewed on appeal. Every ground of rejection set forth in the Office action from which the appeal is taken (as modified by any advisory actions) is being maintained by the examiner except for the grounds of rejection (if any) listed under the subheading "WITHDRAWN REJECTIONS." New grounds of rejection (if any) are provided under the subheading "NEW GROUNDS OF REJECTION."

**(7) Claims Appendix**

The examiner has no comment on the copy of the appealed claims contained in the Appendix to the appellant's brief.

**(8) Evidence Relied Upon**

4477930	Totten et al.	10-1984
4626255	Reichart et al.	12-1986
5928281	Huynh et al	7-1999

**(9) Grounds of Rejection**

The following ground(s) of rejection are applicable to the appealed claims:

Claims 1-8,11-19 are rejected under 35 U.S.C. 102(b) as being anticipated by Totten et al. (4477930). Totten et al. disclose a tubular fabric with a stent frame and a ring insert, see Figs. 1, 6, 7, and col. 4, lines 8-11. Claims in a pending application should be given their broadest reasonable interpretation, *In re Hyatt*, 54 USPQ 2d 1664

(Fed. Cir. 2000). Therefore, the Totten suture ring is configured to pivot or move between two positions since it is made of an elastomer, col. 4, lines 12,13, and Fig. 8, which illustrates that the sewing ring can pivot about the edge. Totten discloses the sewing ring to be pliable or suture permeable (col. 4, line 16), thus it can be interpreted to be bi-stable because of its flexibility and placement at a seam or edge as seen in Fig. 8 and since it will not deform permanently, it is stable when it moves. Additionally, since it is flexible it can be interpreted that it is stable and will not break. The ring can be considered "**generally** frusto-conical" as seen in Figs. 7,10. Totten also discloses the fabric covers the ring and connects the ring to the stent periphery at a seam, col. 5, lines 12-17. Fig. 8 also shows the insert ring to be "substantially" planar.

Claims 9 and 20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Totten '930 in view of Huynh et al. (5928281). Totten is explained supra. However, Totten does not disclose alternating thick and thin regions in the insert ring. Huynh teaches (Figs. 27, 32) that an insert ring for a suture ring is provided with thick and thin regions. It would have been obvious to one of ordinary skill in the art to use thick and thin regions as taught by Huynh in the sewing ring of Totten such that it provides more stability in maintaining the fabric covering to the ring.

Claims 10,21 are rejected under 35 U.S.C. 103(a) as being unpatentable over Totten '930 in view of Reichart et al. (4626255). Totten is explained supra. However, Totten does not disclose the insert ring with a radially undulating shape. Reichart et al. teach (Fig. 1) that the sewing ring has an undulating shape. It would have been obvious to one of ordinary skill in the art to use the undulating shape for the sewing ring as

taught by Reichart with the heart valve of Totten in order to more closely match the shape of the natural annulus to where the prosthetic valve is being implanted.

**(10) Response to Argument**

Appellant presents the argument against the Totten reference stating the limitations of claim 1 are not met. Appellant then details what is believed to be disclosed in the Totten reference. Appellant then presents comments to advantages of the claimed invention and states Totten says nothing about such a feature. However, Appellant never explains in the argument how the feature at issue of the sewing ring being bi-stable is defined or established. Appellant states the Examiner incorrectly interprets the claim and that the claims are not indefinite and cites the MPEP sections for claim language that is acceptable. While claims can be broad and have various interpretations and include functional language, Appellant is reminded the MPEP 2172.01 also states a claim could be incomplete for omitting essential elements that provide the support for the functional language to occur, such omission would amount to a gap between the elements of the invention. This feature of bi-stability Appellant mentions on page 4 of the Brief submitted on 9/22/08 that bi-stable means an element is moveable between two positions. It is the examiner's position because of the structural design of Totten's sewing ring being placed at an edge and is pliable or flexible it is fully capable of moving between two positions about the edge. As a result this would be bi-stable according to Appellant's definition of bi-stable. The examiner is entitled to give terms in a claim its plain meaning as interpreted by one of ordinary skill in the art. It is noted that the specification must clearly set forth the definition of a term

explicitly and with reasonable clarity, deliberateness, and precision. Exemplification is not an explicit definition. Even explicit definitions can be subject to varying interpretations. See *Teleflex, Inc. v. Ficosa North America Corp.*, 63 USPQ2d 1374, 1381 (Fed. Cir. 2002), *Rexnord Corp. v. Laitram Corp.*, 60 USPQ2d 1851, 1854 (Fed. Cir. 2001) and MPEP 2111.01. In addition Appellant states the examiner improperly interprets claim language such as the capability of moving or pivoting from a first position to a second position alleging the examiner gives no weight to the ability to move. This is an incorrect assessment of the examiner's rejection since the examiner clearly establishes how or why the Totten sewing ring is capable of pivoting as described above. It appears Appellant has not followed the examiner's rejection and understood that the term "stable" is a word that describes a condition of an element, but without any comparative measures it has no special meaning. This term has many meanings, i.e. 1) not subject to change 2) does not deteriorate. In considering these general or common definitions it clearly can be said that the pliability of Totten's sewing ring allows for the ring to move without deforming or changing permanently since it is flexible. Additionally since the ring is not made of a degradable material it clearly does not deteriorate. Thus, since the ring moves or pivots the sewing ring can be said to go from one position to another and maintains a stable condition since it will not change or even deteriorate. As a result it can be said that the Totten sewing ring then has two bi-stable positions. The Appellant argues that insufficient weight has been given to the terminology of the claims. This is incorrect. The examiner has merely explained that the sewing ring moves between two positions, but since the claims and specification fail to

establish what defines a "stable" position, the broadest interpretation is given to the terms. Appellant fails to present any comments as to whether a material property or structural feature imparts the bi-stability to the claimed sewing ring. Appellant fails to even explain what structural features in the claims distinguish a difference from Totten's device other than arguing the function of being bistable. Thus, one would look to the specification. The specification states on page 16 that the two positions define "bi-stability". So since such a structure is described to just have the ability to move between two positions, it is bi-stable. Therefore, since Totten's sewing ring can pivot between two positions it is bi-stable and anticipates the claims.

103 rejections over Totten combined with Huynh and also with Reichart

In response to appellant's argument that the examiner's conclusion of obviousness is based upon improper hindsight reasoning, it must be recognized that any judgment on obviousness is in a sense necessarily a reconstruction based upon hindsight reasoning. But so long as it takes into account only knowledge which was within the level of ordinary skill at the time the claimed invention was made, and does not include knowledge gleaned only from the appellant's disclosure, such a reconstruction is proper. See *In re McLaughlin*, 443 F.2d 1392, 170 USPQ 209 (CCPA 1971). Thus, the rejection over Totten and Huynh is maintained.

In response to appellant's argument that there is no suggestion to combine the Totten reference with Reichart, the examiner recognizes that obviousness can only be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so



found either in the references themselves or in the knowledge generally available to one of ordinary skill in the art. See *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988) and *In re Jones*, 958 F.2d 347, 21 USPQ2d 1941 (Fed. Cir. 1992). In this case, it is well known in the prosthetic art that when implanting prostheses, the surgeon often matches a prosthetic surface with the contour of the bone, tissue or organ structure in which the implant is to replace or assist. Common sense would lead a surgeon to match the structures and not have non-congruent structures. A square is not matched up with a triangle, thus one of ordinary skill clearly would look to Reichart to form the sewing ring of Totten with an undulating shape to match the annulus of the heart valve since this is the normal contour around the heart valve.

**(11) Related Proceeding(s) Appendix**

No decision rendered by a court or the Board is identified by the examiner in the Related Appeals and Interferences section of this examiner's answer.

For the above reasons, it is believed that the rejections should be sustained.

Respectfully submitted,

/Brian E Pellegrino/  
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Conferees:

/Corrine M McDermott/  
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